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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 2/2/96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), / days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-21 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-21 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

15. Claims 1-20 are currently pending.

16. Claims 1, 5, 6, 7, and 20 have been amended.

17. Claim 21 is newly added.

18. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. The specification is objected and claim 4 is rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and for failing to adequately teach how to make and/or use the invention, i.e. for failing to provide an enabling disclosure. The specification does not define the anti-fibrotic agents. It appears from the specification that only those anti-fibrotic agents which inhibit the activity of a fibrotic agent will work in the claimed invention. Merely binding an agent with an antibody will have little effect if the antibody will not inhibit the agents activity. Applicant is invited to clarify this issue.

Applicant states that anti-fibriotic agents inhibit scarring or reduce fibrosis. Applicant has pointed to sections of the specification for suport of these definitions. However, the specification refers only to those agents listed in claim 20 as having these attributes. Therefore applicant should limit the claimed invention to the agents listed in claim 20 as amended.

20. The specification is objected and claims 1, 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and for failing to adequately teach how to make and/or use the invention, i.e. for failing to provide an enabling disclosure. The claims are directed to a composition comprising an non-fibrotic growth factor [e.g. TGF-β_1] together with an anti-fibrotic agent [e.g. an antibody to TGF-β_1]. The specification fails to provide any direction for the use of such a composition e.g. the specification fails to provide the concentration of agents. Equimolar amounts of such agents will expectedly bind each other and thereby be rendered useless in such a composition for use in treating wounds.

21. The specification is objected and claims 1, 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and for failing to adequately teach how to make and/or use the invention, i.e. for failing to provide an enabling disclosure. The claims are directed to a composition comprising anti-sence oligonucleotides or ribozymes. However, the specification is devoid of direction on how to use such a composition. There is no direction on how these particular agents are to be directed into the cell nucleus <u>in vivo</u>.

22. Claim 13 is objected to under 37 C.F.R. § 1.75(c) as being in improper form because they depend from a multiple dependent claim, claim 8. See M.P.E.P. § 608.01(n). Accordingly, claim 13 has not been further treated on the merits.

For clarification: Claims 8-11 and 13 were previously objected to under 37 C.F.R. § 1.75(c) as being in improper form because they depend from a multiple dependent claim, claim 5. See M.P.E.P. § 608.01(n). Accordingly, claims 8-11 and 13 have not been further treated on the merits. Applicant states that Claim 5 as originally filed was not a multiple dependent claim. Applicant states that in the September 15, 1994 Preliminary Amendment a request was made to proceed on the 19 claims as originally filed, a copy of the original claims was included with the amendment. The September 15, 1994 amendments were entered into this application. Claim 5 was not amended. This application was filed under 35 U.S.C. § 371. The "original claims" are those 19 claims found at the end of the specification. The preliminary amendment added claim 20. The claims applicant appears to define as "original claims" are believed to be those attached to the preliminary amendment. The Preliminary Amendment at page 1, last sentence states "[t]he originally filed claims are attached to this Amendment for the Examiner's convenience." A proper amendment requesting the entry of these claims into the application was not filed. Therefore, these claims were not entered into the record and the objection was proper.

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 1, 3, 7-11, 17, 18 and newly added claim 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Geistlich et al. [WO 90/03810 (1990)]. Please note a typographical error was made in this rejection claim 6 was inadvertently inserted for claim 7, the rejection does not change in substantively, and therefore a new grounds is not necessary here. Geistlich et al. teach delayed release compositions for wound healing. Such compounds are interspersed in a hydrogel. Geistlich et al. teach the preparation of the hydrogel composition. See abstract and pages 1-4. Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. In re Best, 195 U.S.P.Q. 430, 433 (CCPA 1977). The composition of Geistlich et al. is the same as that claimed. Thus, the Geistlich et al. composition inherently has the same properties as the composition claimed. The burden of proof is on applicant where rejection is based on inherency under 35 U.S.C. 102. Best, at 433.

Applicant states that "Geistlick et al. does not teach or suggest the use of the specific combinations of agents required by applicant's claims. Applicant states that "[n]o teaching in Geistlick et al. relates to non-fibrotic growth factors used alone or used in combination with fibrotic growth factors, and fibrotic growth factors together with anti-fibrotic agents" Applicant concludes that since "Geistlick et al. does not teach each element of" the claims the reference does not anticipate the claimed invention. This is not persuasive. Considering the instant invention -- Claim 1 is drawn to a composition for use

in healing wounds comprising at least one non-fibrotic growth factor with or without fibrotic growth factors in a pharmaceutically acceptable carrier [Geistlich et al. teach this - the abstract clearly states a hydrogel containing one or more gellable proteins . . . containing one or more growth factors selected from epidermal growth factor, human fibroblast growth factor, human insulin-like growth factor and platelet derived growth factor for use in wound healing]. Claim 3 is drawn to FGF, as discussed immediately above Geistlich et al. teach fibroblast growth factor. Claim 17 adds that the carrier is a biopolymer -- Geistlich et al. address this see pages 3-6, and claim 2 of Geistlich et al. Claim 18 is drawn to a preperation of such a composition. Geistlich et al. address this see pages 3-6 of Geistlich et al. Claim 21 is drawn to at least one non-fibrotic growth factor being FGF with at least one fibrotic growth factor. Geistlich et al. teach this see abstract. Claims 8-11 refer to the non-fibrotic factors/agents are present in the composition in an inactive form, by encapsulation, degradeable by external stimulus, including in vivo enzymes or heat. Geistlich et al. teach this at pages 3-6. Application of the hydrogel to the body will inherently result in degradation by in vivo enzymes or heat.

25. Claims 1, 2, 6, 12 and 14-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cerletti et al. [EP 0 433 225 (1990)]. Cerletti et al. teach a method for treating wounds using a TGF-β like protein. See page 5, lines 9-19. Cerletti et al. teach TGF-β like proteins refers to TGF-β_1, TGF-β_2 and TGF-β_3. See page 4, lines 54-56. Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. In re Best, 195 U.S.P.Q. 430, 433 (CCPA 1977). The composition of Cerletti et al. is the same as that claimed. Thus, the Cerletti et al. composition inherently has the same properties as the composition claimed. The burden of proof is on applicant where rejection is based on inherency under 35 U.S.C. 102. Best, at 433.

Applicant makes similar arguments to those made in the above rejection. They are not persuasive. Applicant references TGF-β_3 and states that Cerlitti does not teach the non-fibrotic character of TGF-β_3. However, Cerletti et al. teach a composition comprising TGF-β_3 for use in would healing. Therefore the Cerletti et al. composition of TGF-β_3 inherently has the same properties as the instant claimed invention. Applicant is again refered to Best.

26. No claim allowed.

27. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald E. Adams whose telephone number is (703) 308-0570. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached at (703) 308-3973. The fax phone number for Group 1816 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this

application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

July 1, 1996

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Donald E. Adams, Ph.D.
Primary Examiner
Group 1800